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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,747	02/09/2004	Edward J. Gough	37167-8012.US00	8688

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,747

Applicant(s)

GOUGH ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7-9,11,12,15,18-24,30-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7-9,11,12,15,18-24 and 30-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-9, 11, 12, 15, 18, 18-24, 32, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (5,370,675).

Edwards et al disclose a device comprising an introducer (14) and a plurality of antennas (56) extending through the introducer. The antennas exhibit a changing direction of travel when deployed (see Figures 7-9). Edwards et al disclose that the antennas may be microwave antennas (col. 3, lines 55-63) that may include a slidable outer insulating sleeve. Edwards et al also disclose the use of temperature and impedance sensors for sensing tissue temperature/impedance and controlling the delivery of energy (see col. 4, lines 5+; col. 9, lines 30+; and col. 13, lines 5+). Figure 13 shows a power control console that includes displays (176) for showing the monitored temperature and impedance values. Edwards et al disclose that fluid can be supplied through the stylets or through a central channel in the introducer. The method of using the device to ablate tissue is fully disclosed by Edwards et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-9, 11, 12, 15, 18-24 and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al (5,827,276) in view of the teaching of Edwards et al ('675).

LeVeen et al disclose a system that includes an introducer (12) and a plurality of antennas (24) positioned in the introducer and deployable therefrom with a changing direction of travel (i.e. curved). LeVeen et al teach that the antennas are RF electrodes, not microwave antennas, and fail to disclose thermal sensors.

Leveen et al do teach that the introducer is more rigid than the antennas (see Figures) and that the introducer is rigid enough to be introduced through tissue (Figure 4). Also, a slidable insulation sleeve (Figure 8) is provided around each electrode to create a desired ablation volume. LeVeen et al also teach that the introducer may be provided with an electrode (340 – Figure 7 or first set of electrodes 28b in figure 5) connected to the energy source.

With regard to the microwave antennas, the previously addressed Edwards et al device is a substantially identical device that includes an introducer with a plurality of stylets deployable therefrom. Edwards et al specifically disclose the well-known substitution of RF electrodes for microwave antennas in such a system to provide an alternative energy delivery modality for treating tissue. Moreover, applicant's own specification indicates the ready substitution of RF electrodes for microwave antennas and makes no statement of criticality for using one modality in favor of the other. Edwards et al also teach of providing temperature sensors to monitor temperature and

control the delivery of energy accordingly, as well as the use of infusion to provide treatment and cooling fluids to tissue.

To have provided the LeVeen et al system with microwave antennas in lieu of the RF electrodes as an alternative treatment modality would have been an obvious consideration for one of ordinary skill in the art, particularly since Edwards et al teach that such a substitution is generally known in the art. To have further provided the LeVeen et al system with a temperature feedback control system and fluid delivery capability to control tissue parameters during treatment would have been an obvious modification for one of ordinary skill in the art in view of the Edwards et al.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al ('276) and Edwards et al ('675) and further in view of the teaching of Edwards et al (5,507,743).

The combination of the Edwards et al teaching of using microwave antennas or RF electrodes to treat tissue and temperature sensors to control the delivery of energy has been previously addressed. The examiner maintains that LeVeen et al disclose providing an introducer that has an electrode (Figures 5 and 7). The electrodes in Figure 5 both deliver RF energy, but the examiner maintains that to have provided one set as microwave electrodes and the other set as RF electrodes would have been an obvious consideration in view of the Edwards et al ('675) teaching. However, to further support such an assertion, attention is directed to the Edwards et al ('743) device that includes an introducer and a plurality of deployed electrodes. In particular, Edwards et

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al teach that the outer electrode may delivery microwave energy to heat peripheral tissue while RF energy is delivered to the inner electrode to ablate tumor tissue. The examiner maintains that this is a clear teaching of using two separate energy modalities for the treatment of tumor tissue.

To have provided the LeVeen et al system with set of microwave antennas as well as a set of RF electrodes to treat the tumor tissue with two different energy modalities would have been an obvious consideration for one of ordinary skill in the art, particularly in view of the teaching of Edwards et al ('743).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3,7-9,11,12,15,18-24 and 30-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of the following U.S. Patent Numbers: 5,672,173; 5,672,174; 5,728,143; 5,913,855;

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5,928,229; 5,951,547; 5,980,517; 6,080,150; 6,132,425; 6,689,127; 6,958,062; 5,735,847; 5,782,827; 5,863,290. Although the conflicting claims are not identical, they are not patentably distinct from each other because these numerous patents all claim the same essential device with obvious variations (e.g. curvature of antenna, type of energy delivered, shape of introducer, etc.). The inventions in the above patents represent basically a matrix of elements in a variety of arrangements and were, by and large, patentable for the same general reasons. It is noted that a number of Terminal Disclaimers between the above cited patents have been filed.

Claims 1-3,7-9,11,12,15,18-24 and 30-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 11/016,384 in view of the teaching of LeVeen et al (5,827,276). Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of a trocar as the introducer is deemed to be an obvious choice in accessing tumor sites, particularly since LeVeen et al disclose an analogous system that uses either a regular introducer (12) or a trocar (502 – Figure 13) for providing the device to tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

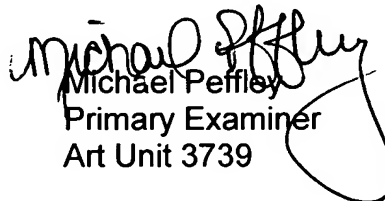
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
May 24, 2006